DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 9, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 06

Alfred A. Iversen
President
PMT Corporation
1500 Park Road
Chanhassen, Minnesota 55317

Dear Mr. Iversen:

During an inspection of your establishment located in Chanhassen, MN, on July 17-18, 20, 24-25 and 31, 2001, our investigators determined that your establishment manufactures external neck fixation systems, tissue expanders, electrodes and other products which are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820).

Quality system deficiencies were observed in the areas of management responsibility, quality audits, corrective and preventive action, complaint handling, device history records, and production and process controls. Deficiencies include, but are not limited to:

A. Procedures for conducting quality audits are not complete (21 CFR 820.22). For example, written audit reports are not distributed to management having responsibility for the matters audited.

B. Procedures for implementing corrective and preventive actions are not complete (21 CFR 820.100). For example, there is no documentation to

show that quality indicators are appropriately monitored to detect recurring quality problems.

C. Complaint handling procedures for receiving, reviewing and evaluating complaints are not always followed [21 CFR 820.198(a)]. For example, the "Action Taken" section of complaint investigation reports is not always being completed.

D. Device history records are not complete and accurate (21 CFR 820.184). For example, the device history record for Model 3608-03 Remote Port, lot number 021901, contains inconsistencies in the number of devices produced.

E. Schedules for the adjustment, cleaning and other maintenance of equipment are not followed [21 CFR 820.70(g)(1)]. Specifically, maintenance requirements are not being met for package sealing equipment.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

We have received Eric Caille's August 31, 2001, response to the form FDA-483 issued on July 31, 2001. The corrective actions that you have taken or plan to take appear to be adequate with one notable exception. We are concerned that your plans may not fully address the need to have adequate resources, including sufficient well-trained personnel, to achieve and maintain compliance with the

Quality System regulation. We ask that you address this concern in your written reply to this Warning Letter. In addition, please notify our office when you have completed your corrective actions. We will conduct a follow-up inspection in the near future to check the implementation and effectiveness of your corrections.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Compliance Officer Timothy G. Philips at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl